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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,340	06/27/2001	Robert A. Rousseau	ETH-1507	3554

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EXAMINER

GILPIN, CRYSTAL M

ART UNIT PAPER NUMBER

3738

DATE MAILED: 05/15/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K.

Office Action Summary

Application No.

09/892,340

Applicant(s)

ROUSSEAU, ROBERT A.

Examiner

Crystal M Gilpin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claim 16 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

1. Claims 1 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Amid et al. (WO 02/07648).

Regarding claims 1 and 16, Amid et al. teach of a flexible biocompatible material with a plurality of interstices, comprising a mesh, for implantation in the body (Page 2, Lines 20-28). Amid et al. further teach that the mesh includes ridges or pleats that extend substantially perpendicularly from the mesh surface (Fig. 9) which facilitate the movement of the material from a collapsed or pleated state to a flat or expanded shape (Page 10, Lines 23-28). The ridges are part of the body portion (Fig. 1, Ref. #24) of the prosthesis, which is made of the same material as the anchoring portion (Fig. 1, Ref. # 26) of the prosthesis and therefore the ridges are not more rigid than the mesh material.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 2-6, 14, 15, and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amid et al. (WO 02/07648) in view of Mulhauser et al. (USPN 5,766,246).

Regarding claims 2 and 17, Amid et al. lack the teaching of forming the ridge by a thermo-process. Mulhauser et al. teach of a prosthetic mesh with a ridge or ring (Figure 1, Reference number 14) may be formed by hot or cold forming (Column 4, Lines 60-65), thus comprising a thermo-forming process. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Amid et al. to make

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the ridge by a thermo-forming process so that a portion of the implant would be stiff enough to be properly handled in surgery.

Regarding claims 3 and 18, Amid et al. teach that the ridges are expandable (Page 10, Lines 27-28).

Regarding claim 4, Amid et al. disclose that it is well known in the art to use an implant prosthesis of biocompatible material, such as his invention, for the repair of hernias (Page 1, Lines 9-12).

Regarding claim 5, Amid et al. lack the teaching of the mesh being circular. Mulhauser et al. teach of a prosthetic mesh that is circular in order to define a boundary that surrounds the hernia defect. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Amid et al. to have a circular prosthetic mesh in order to properly repair the hernia defect.

Regarding claim 6, 14 and 19, Amid et al. teach of a plurality of ridges (Figure 9, Ref. # 56).

Regarding claim 15, Amid et al. teaches of ridges that extend linearly between the edges of the mesh (Figure 8, Ref. # 56).

3. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Amid et al. (WO 02/07648) in view of Mulhauser et al. (USPN 5,766,246) and in further view of Kugel (USPN 5,634,931).

Regarding claim 7, both Amid et al. and Mulhauser et al. teach of a prosthetic mesh, however they both lack the teaching of a mesh with two layers. Kugel teaches of a hernia mesh patch (Entire article, specifically Column 7, Lines 36-60) composed of a top (Figure 5,

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Reference number 42) and bottom layer (Figure 5, Reference number 44) connected by a ring (Figure 5, Reference number 72). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Amid et al. to connect two mesh layers to provide a pouch used for ease of placement (i.e. with a finger) of the prosthetic.

4. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amid et al. (WO 02/07648) in view of Mulhauser et al. (USPN 5,766,246), in further view of Kugel (USPN 5,634,931) and in further view of Kugel (USPN D416,327).

Regarding claims 8 and 9, both Amid et al. and Mulhauser et al. teach of prosthetic meshes with ridges, however they lack the teaching of multiple ridges and different ridge formations. Kugel (USPN D416,327) teaches of two concentric ring shaped ridges. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Amid et al. to have ridges in the shape of concentric rings or other designs to provide sufficient stiffness and strength for the mesh material.

Kugel (USPN D416,327) does not expressly disclose the limitations of claim 10. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Kugel to include ridges of a different shape because Applicant has not disclosed that the varying shapes of ridges provides an advantage, is used for a particular problem, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a concentric ring

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shaped ridges because it provides sufficient stiffness and strength to keep the mesh in the preferred flat shape.

Therefore, it would have been an obvious matter of design choice to modify the invention of Amid et al. to obtain the invention as specified in claim 10.

5. Claims 11-13 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amid et al. (WO 02/07648) in view of Mulhauser et al. (USPN 5,766,246) and in further view of Kugel (USPN D416,327).

Regarding claims 11, 12 and 20, both Amid et al. and Mulhauser et al. teach of prosthetic meshes with ridges, however they lack the teaching of multiple ridges and different ridge formations. Kugel teaches of two concentric ring shaped ridges. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of de la Torre to have ridges in the shape of concentric rings or other designs to provide sufficient stiffness and strength for the mesh material.

Kugel (USPN D416,327) does not expressly disclose the limitations of claim 13. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Kugel to include ridges of a different shape because Applicant has not disclosed that the varying shapes of ridges provides an advantage, is used for a particular problem, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a concentric ring shaped ridges because it provides sufficient stiffness and strength to keep the mesh in the preferred flat shape.

Therefore, it would have been an obvious matter of design choice to modify the invention of Amid et al. to obtain the invention as specified in claim 13.

Response to Arguments

Applicant's arguments, see Paper No. 5, filed 21 March 2003, with respect to the rejection(s) of claim(s) 1 under U.S.C. 102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Amid et al. (WO 02/07648).

Applicant's arguments with respect to claims 11 and 12 have been considered but are not persuasive and are moot in view of the new ground(s) of rejection. Although Kugel (D416,327) does not expressly disclose exactly what the ring structure is, it is clear from the figures that the ring protrudes from the mesh surface creating a ridge.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Crystal M Gilpin whose telephone number is 703-305-8122. The examiner can normally be reached on M-F, 8-5 (First Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9301 for regular communications and 703-872-9301 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

cmg
May 12, 2003


Paul B. Prebitt
Primary Examiner